OLYMPUS®

INSTRUCTIONS

OLYMPUS
EndoTherapy

MECHANICAL LITHOTRIPTOR
BML-110A-1

AUTOCLAVABLE

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.	CE

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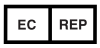
Symbols

The meaning(s) of the symbol(s) shown on the package, the back cover of this instruction manual and/or this instrument are as follows:

Refer to instructions.

Manufacturer



Authorised representative in the European Community

Important Information — Please Read Before Use

Intended Use

This instrument has been designed to be used with an Olympus lithotriptor and basket type Grasping Forceps for crushing biliary calculi in the bile duct and removing the basket from the patient. This instrument should be used when the basket cannot be removed from the patient through normal procedures. Do not use this instrument for any purpose other than its intended use.

Instruction Manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which will be used during the procedure and use the instruments as instructed.
Keep this and all related instruction manuals in a safe, accessible location.
If you have any questions or comments about any information in this manual, please contact Olympus.

User Qualifications

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures.

Instrument Compatibility

Refer to the Table in Section 2.2, “Specifications” to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient injury or equipment damage.

Reprocessing and Storage

This instrument was not sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions in Chapter 5, “Reprocessing”.

After using this instrument, reprocess and store it according to the instructions in Chapter 5, “Reprocessing” and Chapter 6, “Storage”. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause equipment damage or reduce performance.

Repair and Modification

This instrument does not contain any user-serviceable parts. Do not disassemble, modify or attempt to repair it; patient or user injury and/or equipment damage can result.

Signal Words

The following signal words are used throughout this manual:

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

NOTE

Indicates additional helpful information.

Warnings

Follow the warning described below when handling this instrument. This information is to be supplemented by the warnings described in each chapter.

WARNING

- Before use, thoroughly review the method of use for lithotriptor BML-110A-1 in accordance with the instruction manuals.
- Do not use this lithotriptor BML-110A-1 for a calculus that is assumed impossible to be crushed by this lithotriptor. The basket wire etc. may break and part of this lithotriptor may remain in the body.

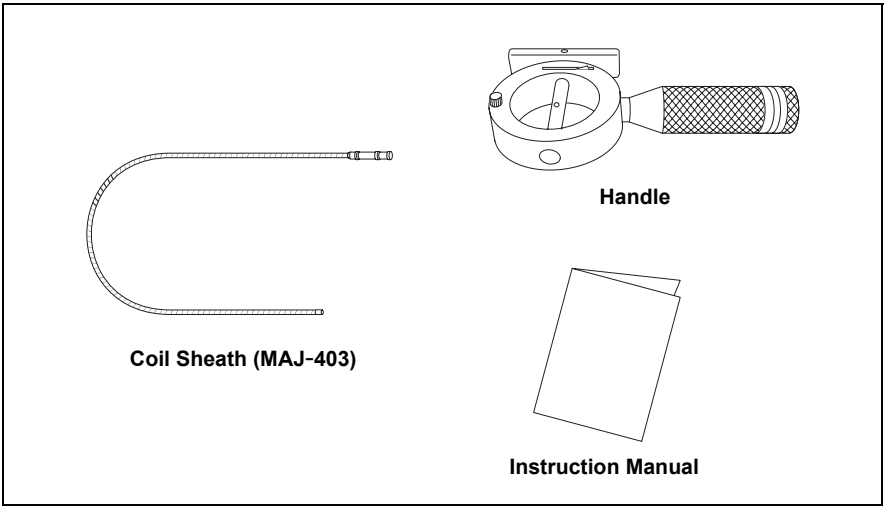
- Use this instrument by having the settings to switch to open surgery and the hospitalization plan ready in case the calculus cannot be crushed by lithotriptor BML-110A-1.
- Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure. If the calculus is too hard, it is possible that the damages shown in Chapter 4, “Emergency Treatment” may occur. Use this instrument by considering that it may lead to damaging the Grasping Forceps and that open surgery may have to take place.

Chapter 1 Checking the Package Contents

1.1 Checking the Package Contents

Match all items in the package with the components shown below. Inspect each item for damage. If the instrument is damaged, a component is missing or you have any questions, do not use the instrument; immediately contact Olympus.
This instrument was not sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions in Chapter 5, “Reprocessing”.

❍ Set



❍ Coil Sheath (MAJ-403)

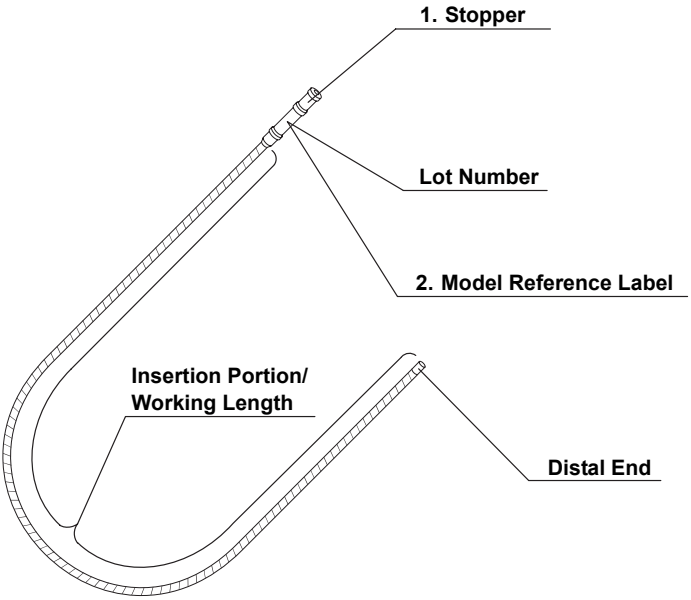
Coil Sheath (1 piece)

Chapter 2 Instrument Nomenclature and Specifications

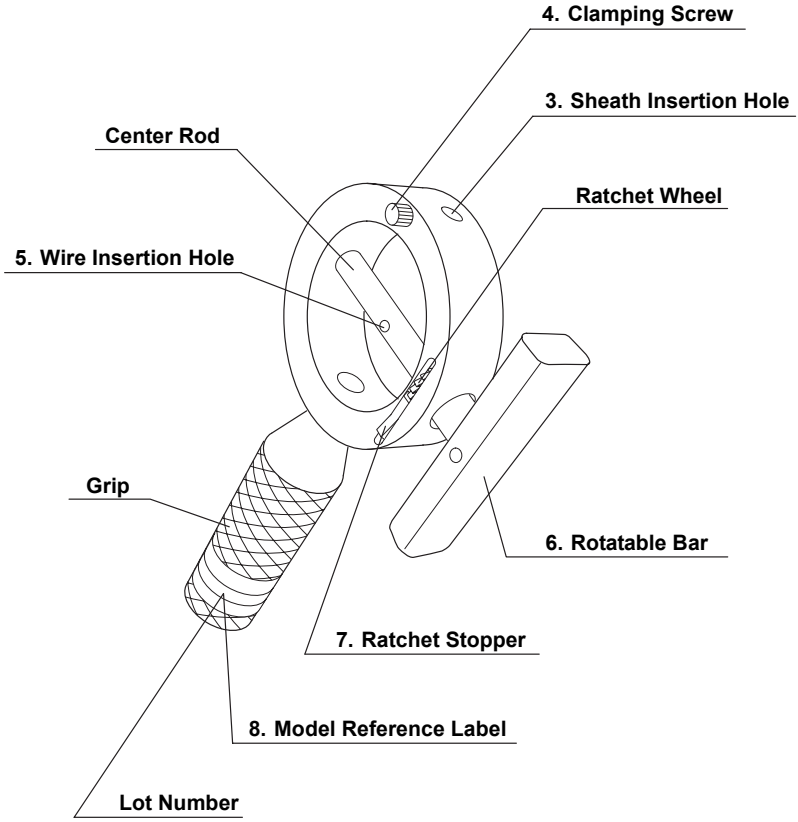
2.1 Nomenclature and Functions

This instrument consists of a Coil Sheath and a Handle. This instrument must be used in combination with the wire of the Mechanical Lithotriptor or basket type Grasping Forceps.

❍ Coil Sheath



❍ Handle


4. Clamping Screw
3. Sheath Insertion Hole
Center Rod
Ratchet Wheel
5. Wire Insertion Hole
Grip
6. Rotatable Bar
7. Ratchet Stopper
8. Model Reference Label
Lot Number

1. **Stopper**
   Fits into the Handle's Sheath Insertion Hole to prevent separation of the Coil Sheath from the Handle.
2. **Model Reference Label**
   Indicates the product number.
   A green reference label indicates that the instrument is autoclavable.
3. **Sheath Insertion Hole**
   Holds the Stopper of the Coil Sheath to prevent separation of the Coil Sheath from the Handle.
4. **Clamping Screw**
   Tightened to fix the Stopper of the Coil Sheath.
5. **Wire Insertion Hole**
   Insert the wire here to coil it onto the Center Rod.
6. **Rotatable Bar**
   When turned, this coils the wire onto the Center Rod.
7. **Ratchet Stopper**
   Engages the Ratchet Wheel to prevent the Center Rod from reversing.
8. **Model Reference Label**
   Indicates the product number.
   A green reference label indicates that the instrument is autoclavable.

2.2 Specifications

The compatible Olympus Endo-Therapy Accessories are listed in the Table on the following page. New Endo-Therapy Accessories released after the introduction of this instrument may also be compatible for use in combination with this instrument. For further details, contact Olympus.

WARNING

- Use this instrument only in combination with products recommended by Olympus. If combined with products not recommended by Olympus, patient or operator injury,malfunction or equipment damage may result.
- Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure. If the calculus is too hard, it is possible that the damages shown in Chapter 4, “Emergency Treatment” may occur. Use this instrument by considering that it may lead to damaging the Grasping Forceps and that open surgery may have to take place.

Operating Environment

Ambient Temperature	10 – 40°C (50 – 104°F)
Relative Humidity	30 – 85%
Air Pressure	700 – 1060 hPa (0.71 – 1.08 kgf/cm^2) (10.1 – 15.4 psia)

Specifications

Model	**BML-110A-1**
Shape of the Distal End	
Maximum Insertion Portion Diameter (mm)	ø 3.9

Working Length (mm)	900
Compatible Olympus Basket Type Grasping Forceps and Mechanical Lithotriptors	FG-22Q-1, FG-23Q-1, FG-301Q, FG-401Q, FG-402Q, FG-403Q, FG-V401QR, FG-V402QR, FG-V411Q, FG-V412Q, BML-1Q-1, BML-2Q-1, BML-3Q-1, BML-4Q-1, BML-201Q, BML-202Q, BML-203Q, BML-204Q, BML-V232QR-26, BML-V232QR-30, BML-V237QR-30, BML-V242QR-30, BML-V437QR-30, BML-V442QR-30

Medical Device Directive	CE	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class I

Chapter 3 Preparation, Inspection and Operation

WARNING

- Before each case, prepare and inspect the instrument as instructed below. Inspect other equipment to be used with the instrument as instructed in their respective instruction manuals. Should the slightest irregularity be suspected, do not use the instrument; contact Olympus. Damage or irregularity may compromise patient or user safety, such as an infection control risk, tissue irritation, punctures, hemorrhages or mucous membrane damage and may result in more-severe equipment damage.
- The instrument was not sterilized before shipment. Before using the instrument for the first time, reprocess it according to the instructions in Chapter 5, “Reprocessing”.
  Do not use an instrument that has not been cleaned and sterilized. This poses an infection control risk and can cause tissue irritation.

CAUTION

Do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.

3.1 Preparation

Equipment and Personal Protective Equipment

Prepare all equipment and personal protective equipment which will be used with the instrument in accordance with their respective instruction manuals. Appropriate personal protective equipment may include: Eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves. Also have pliers or wire cutters ready; you will need them to cut the sheath and wire of the Grasping Forceps or Mechanical Lithotriptor.

Spare Instrument

Always have a spare instrument available.

Reprocessing Equipment

Prepare reprocessing equipment as described in Section 5.2, “Required Reprocessing Equipment” for immediate reprocessing after use.

3.2 Inspection

Wear the personal protective equipment as specified in the Table on page 38.

Before each case, always inspect the instrument according to the following procedures.
If an abnormality in the instrument is detected, use a spare instrument, inspecting it thoroughly before use.

Inspection of the Sterile Package

Inspect the sterile package for tears, inadequate sealing or water damage. If the sterile package shows any irregularities, the sterile condition of the instrument may have been compromised. Use a spare instead.

Appearance Inspection

If any of following steps reveals irregularities, do not use the instrument; use a spare instead.

WARNING

Before use, carefully inspect the entire coil sheath as instructed in this chapter; confirm that it is not crushed, bent, deformed or otherwise damaged. A damaged coil sheath may not be able to properly crush a calculus and/or it could cause the instrument to break.

❍ Inspecting the Coil Sheath

1. Make sure that the Distal End and Stopper of the Coil Sheath are free from disconnection or looseness.
2. Gently run your fingertips over the entire length of the Insertion Portion to check for any crushed areas, excessive bends, sharp protrusions, sharp edges.
3. Make sure that there are no sharp protrusions, sharp edges or other apparent malformations at the Distal End of the Insertion Portion. Confirm that the Distal End of the Insertion Portion appears exactly as shown in the Table in Section 2.2, “Specifications” and is not damaged.

❍ Inspecting the Handle

1. Make sure that the Handle's Sheath Insertion Hole and Wire Insertion Hole are undamaged and free of any foreign matter.
2. Make sure that there are no cracks on the Handle.

Inspecting the Connections

WARNING

Make sure to have the stopper and the BML handle connected. If the instrument separates from the BML handle during operation, the pipe may break or become uncontrollable. Also, the coil sheath and wire with calculus engaged may not be removed from the body.

CAUTION

Due to this instrument's construction, the Ratchet Stopper of the Handle has a sharp tip. To avoid injury, be very careful when handling this instrument.

If any of following steps reveals irregularities, do not use the instrument; use a spare instead.

1. Loosen the Clamping Screw of the Handle by turning it counterclockwise until it stops.
2. Insert the Coil Sheath's Stopper as far as possible into the Handle's Insertion Hole (see Figure 3.1).
3. Tighten the Handle's Clamping Screw by turning it clockwise until it stops (see Figure 3.1).
4. Push and pull the Stopper to make sure the Stopper is securely attached to the Handle.
5. Loosen the Clamping Screw by turning it counterclockwise until it stops and remove the Coil Sheath.

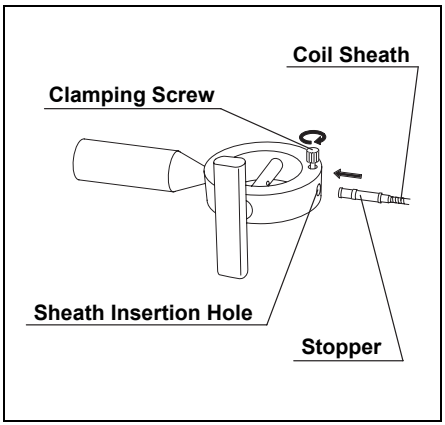


Figure 3.1

Inspection of Operation

WARNING

After assembly, check that no abnormality is detected in the action of the handle. If there is any abnormality, the calculus may not be crushed and/or the coil sheath and wire with stone engaged may not be removed from the body.

CAUTION

Due to this instrument's construction, the Ratchet Stopper of the Handle has a sharp tip. To avoid injury, be very careful when handling this instrument.

If any of following steps reveals irregularities, do not use the instrument; use a spare instead.

1. To make sure the Rotatable Bar and Center Rod rotate smoothly, turn the Rotatable Bar in the direction of the arrow as shown in Figure 3.2.

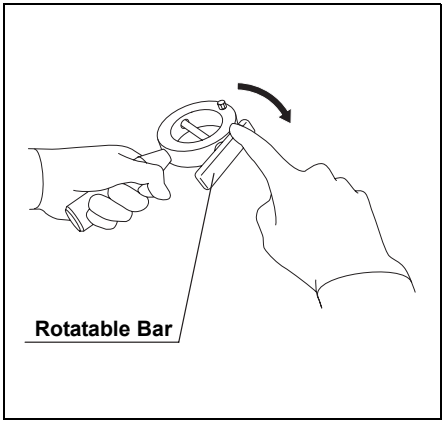


Figure 3.2

2. Push the Ratchet Stopper with your finger. Confirm that it operates smoothly (see Figure 3.3).

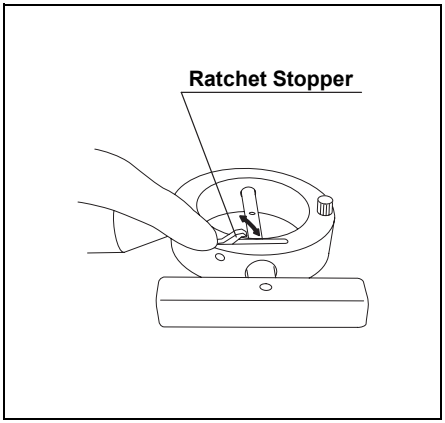


Figure 3.3

3. Engage the Ratchet Stopper. Confirm that the Ratchet Stopper is working properly by attempting to turn the Rotatable Bar in the direction of the arrow as shown in Figure 3.4. The Ratchet Stopper should prevent the Rotatable Bar from being turned in this direction.

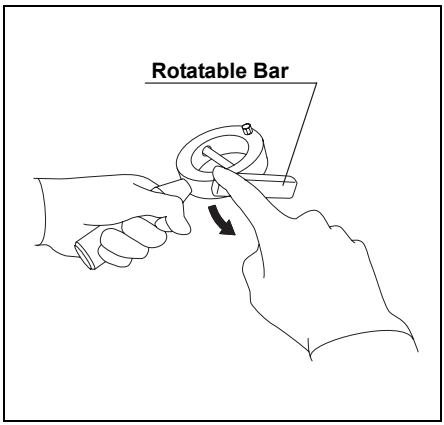


Figure 3.4

3.3 Operation

The operator of the instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique.
This manual, therefore, does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this instrument.

WARNING

- Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure. In the course of crushing a hard calculus, the pipe and/or the basket wire could break and fall off of the instrument inside the patient. If the pipe or basket wire is damaged during use, immediately stop using the instrument and follow the appropriate instruction(s) given in Chapter 4, “Emergency Treatment”.

- When using the instrument, always wear appropriate personal protective equipment. Otherwise, blood, mucous and other potentially infectious material from the patient could pose an infection control risk. Appropriate personal protective equipment may include: Eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.
- If you cannot see the Insertion Portion in the X-ray images, do not use the instrument. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage. It may also damage the instrument.
- Do not force the Distal End of the Insertion Portion against body cavity tissue. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
- Do not pull the wire with excessive force. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
- Do not withdraw the coil sheath and wire with stone engaged from the bile duct abruptly and/or with excessive force. This could cause punctures, hemorrhages, mucous membrane damage or edema.

- After cutting the wire, be careful not to touch the proximal end of the wire. Infectious substances attached to the proximal end of the wire such as the patient's blood or mucous, could pose an infection control risk and/or cause operator injury.

Withdrawing the Endoscope

WARNING

Do not withdraw the endoscope and sheath from the body cavity quickly. This could scatter blood, mucous or other patient debris and pose an infection control risk.

NOTE

When cutting the sheath and wire of the Grasping Forceps or Mechanical Lithotriptor, leave as much wire as possible to attach to the Handle of this instrument. If the wire is too short, it may not be possible to perform the procedure.

1. Cut the sheath and wire near the handle using pliers or wire cutters.
2. If the Operation Pipe remains on the wire after it has been cut, remove the Operation Pipe with the pliers or wire cutters (see Figure 3.5).

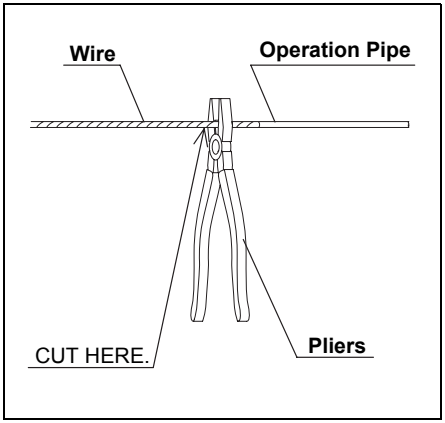


Figure 3.5

3. Withdraw the endoscope and sheath from the body cavity.

Insertion Into the Body Cavity

1. Put the Distal End of the Coil Sheath over the wire (see Figure 3.6).

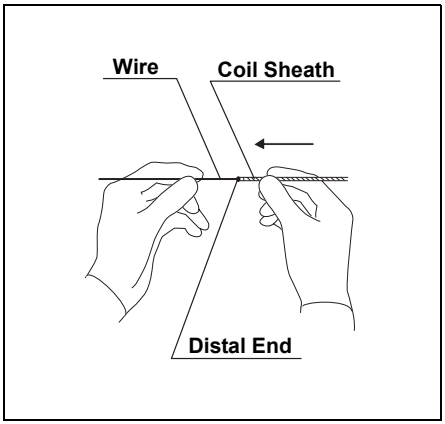


Figure 3.6

2. When the end of the wire comes out of the Stopper of the Coil Sheath, hold the wire as shown in Figure 3.7. Insert the Insertion Portion slowly into the body cavity while monitoring it in the X-ray images, until its Distal End contacts the target calculus.

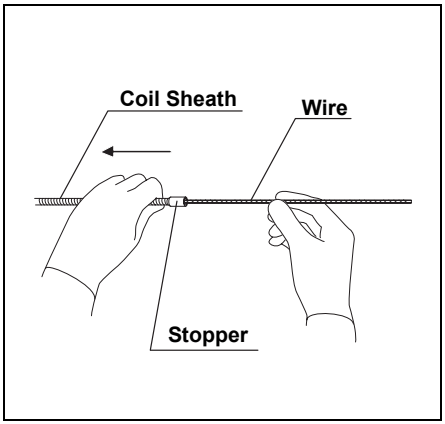


Figure 3.7

Connecting the Handle

WARNING

Have all the wires tightened when setting the wires to the handle. If not tightened, wires may break, the calculus may not be crushed, and/or the coil sheath and wire with calculus engaged may not be removed from the body.

CAUTION

- Due to this instrument's construction, the Ratchet Stopper of the Handle has a sharp tip. To avoid injury, be very careful when handling this instrument.

- Make sure that the Coil Sheath's Stopper is securely attached to the Handle. If the calculus is too hard, the wire may break and pop out of the Stopper of the Coil Sheath. This could cause patient, operator and assistant injury.

1. Loosen the Clamping Screw of the Handle by turning it counterclockwise until it stops.
2. Insert the wire into the Handle's Sheath Insertion Hole and Wire Insertion Hole.
3. While holding the wire to prevent it from being drawn into the body cavity, move the Handle along the wire until the Handle touches the Stopper of the Coil Sheath (see Figure 3.8).

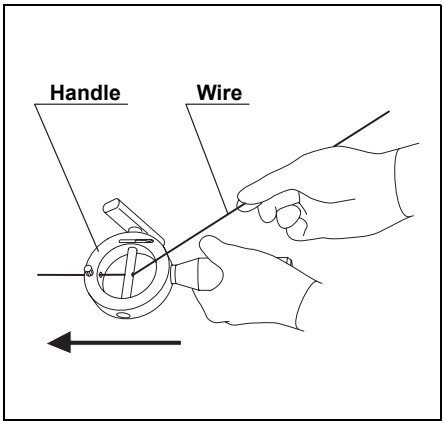


Figure 3.8

4. Insert the Stopper of the Coil Sheath into the Sheath Insertion Hole of the Handle.
5. Tighten the Handle's Clamping Screw by turning it clockwise until it stops.
6. Push and pull the Stopper to make sure the Stopper is securely attached to the Handle.

7. With the Ratchet Stopper of the Handle facing up, hold the Grip of the Handle and the excessive wire with your left hand (see Figure 3.9).

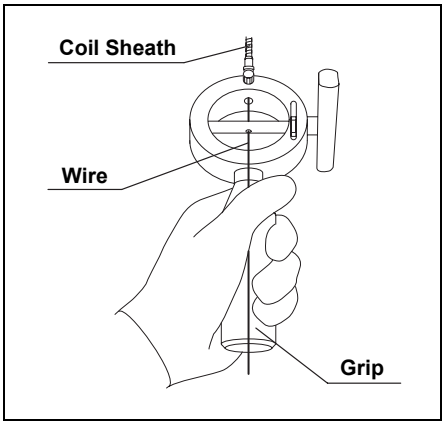


Figure 3.9

Crushing the Calculus

WARNING

- During lithotripsy, keep the portion; from the patient esophagus to the coil sheath and the handle, straight as much as possible. If not straight, the coil sheath may bend, the calculus may not be crushed, and/or the coil sheath and wire with calculus engaged may not be removed from the body.
- Do not push or pull the Coil Sheath and Handle with excessive force during lithotripsy. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.

- Do not withdraw the Insertion Portion and wire from the body cavity quickly. This could scatter blood, mucous or other patient debris and pose an infection control risk.
- During lithotripsy, turn the rotable bar of the handle slowly. If rotated quickly, the wire may break and/or the calculus may not be crushed. Also, the coil sheath and wire with calculus engaged may not be removed from the body.
- Do not withdraw the coil sheath and wire abruptly from the bile duct. It could cause mucous membrane damage or edema.

CAUTION

- Do not operate the Handle above the patient's face. If the calculus is too hard, the wire may break and pop out of the Sheath Insertion Hole inside the Handle (see Figure 3.10). This could cause patient injury.

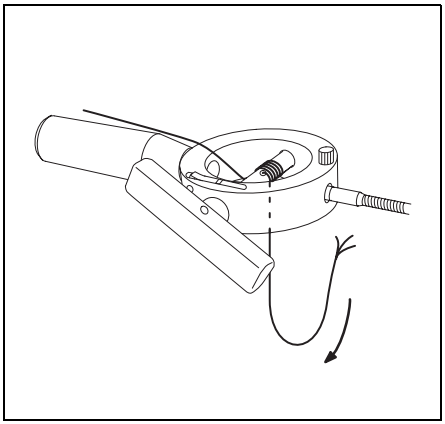


Figure 3.10

- Do not release the Ratchet Stopper of the Handle during lithotripsy. The Rotatable Bar of the Handle could spin rapidly and hurt your hand.
- Do not tilt the Handle significantly during lithotripsy. The Ratchet Stopper of the Handle could spontaneously release, allowing the Rotatable Bar of the Handle to spin rapidly and hurt your hand.
- After crushing the calculi, do not draw too much wire into the Insertion Portion. This could break the wire and make it impossible to withdraw the wire from the body cavity.
- Due to this instrument's construction, the Ratchet Stopper of the Handle has a sharp tip. To avoid injury, be very careful when handling this instrument.

1. While keeping the Coil Sheath and Handle straight (confirm the position of the Insertion Portion, basket and calculus in the X-ray images), slowly turn the Rotatable Bar of the Handle away from you to crush the calculus.
2. When lithotripsy is finished, keep turning the Rotatable Bar of the Handle away from you to pull the basket into the Insertion Portion.
3. While holding the Handle and Coil Sheath, withdraw the Insertion Portion slowly from the body cavity.

Detaching

WARNING

Do not withdraw the wire from the Coil Sheath quickly. This could scatter blood, mucous or other patient debris and pose an infection control risk.

CAUTION

Due to this instrument's construction, the Ratchet Stopper of the Handle has a sharp tip. To avoid injury, be very careful when handling this instrument.

1. Loosen the Clamping Screw of the Handle by turning it counterclockwise until it stops.
2. Push the Ratchet Stopper of the Handle to release it.

NOTE

If the Ratchet Stopper of the Handle is too tight and cannot be released, turn the Rotatable Bar of the Handle slightly away from you, then press the Ratchet Stopper again to release it.

3. While pulling the Coil Sheath, turn the Rotatable Bar of the Handle as shown in Figure 3.11 to remove the wire from the Handle.

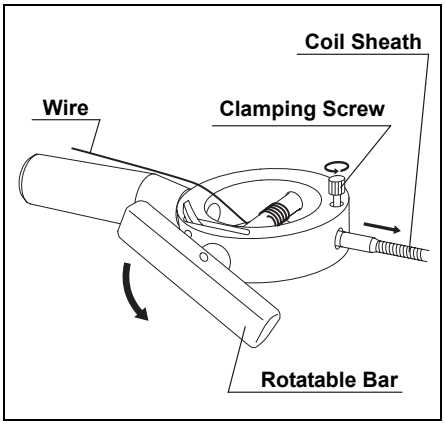


Figure 3.11

4. Using pliers or wire cutters, cut the wire extending from the Stopper of the Coil Sheath.
5. Straighten the Coil Sheath. Then, hold the Basket Tip and slowly withdraw the wire completely.

Disposal of Used Basket Wire

WARNING

After use, dispose of the wire in an appropriate manner. If it is not properly disposed of, it could pose an infection control risk.

After using the wire, dispose of it in an appropriate manner.

Chapter 4 Emergency Treatment

4.1 Emergency Treatment

If the calculus is too hard and the wire or Coil Sheath is damaged to such an extent that lithotripsy cannot be continued, follow the procedure described in this chapter. You can easily feel when the wire or Coil Sheath is damaged because the resistance of the Rotatable Knob of the Handle will suddenly decrease.

WARNING

- Before use, thoroughly review the method of use for lithotriptor BML-110A-1 in accordance with the instruction manuals.
- Do not use this lithotriptor BML-110A-1 for a calculus that is assumed impossible to be crushed by this lithotriptor. The basket wire etc. may break and part of this lithotriptor may remain in the body.
- Use this instrument by having the settings to switch to open surgery and the hospitalization plan ready in case the calculus cannot be crushed by lithotriptor BML-110A-1.
- Do not withdraw the Insertion Portion and wire from the body cavity quickly. This could scatter blood, mucous or other patient debris and pose an infection control risk.

CAUTION

Due to this instrument's construction, the Ratchet Stopper of the Handle has a sharp tip. To avoid injury, be very careful when handling this instrument.

When the Operation Wire is Cut (Figure 4.1)

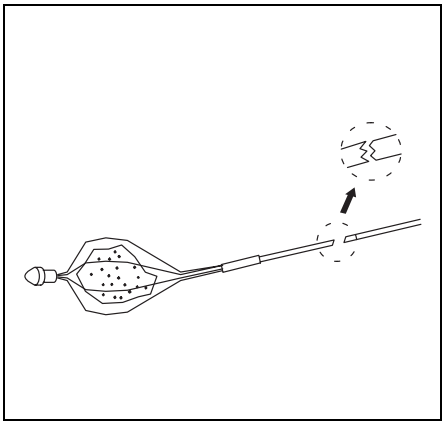


Figure 4.1

1. Withdraw the Insertion Portion and wire from the body cavity.
2. Perform open surgery or other possible treatment.

When the Operation Wire is Not Cut

❍ All of the Basket Wires are Cut (Figure 4.2)

WARNING

- If the broken wires of the Basket Wire cannot be retracted into the Insertion Portion, do not withdraw the Insertion Portion and wire with excessive force. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.
- Do not withdraw the instrument or its fall-offs of the instrument from the bile duct with excessive force This could cause punctures, hemorrhages, mucous membrane damage or edema.

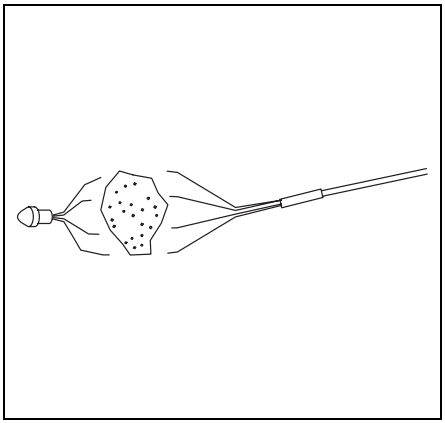


Figure 4.2

1. While holding the Coil Sheath, pull the wire and Handle to draw the wire into the Insertion Portion.
2. Withdraw the wire and Insertion Portion slowly from the body cavity.
3. Perform open surgery or other possible treatment.

❍ Some of the Basket Wires are Cut (Figure 4.3)

WARNING

If the broken wires of the Basket Wire cannot be retracted into the Insertion Portion, do not withdraw the Insertion Portion and wire with excessive force. This could cause patient injury, such as punctures, hemorrhages or mucous membrane damage.

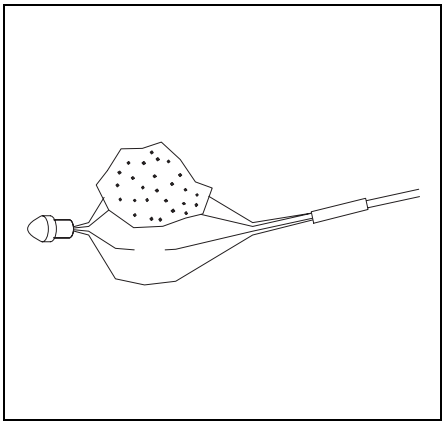


Figure 4.3

1. Turn the Rotatable Bar of the Handle away from you to pull the wire into the Insertion Portion.
2. Withdraw the wire and Insertion Portion slowly from the body cavity.

❍ The Calculus is Outside of the Basket, Which is Still Intact (Figure 4.4)

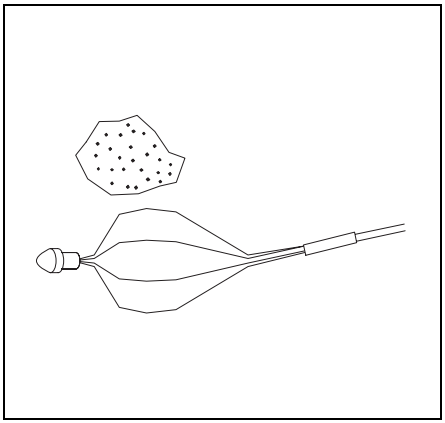


Figure 4.4

1. Turn the Rotatable Bar of the Handle away from you to pull the wire into the Insertion Portion.
2. Withdraw the wire and Insertion Portion slowly from the body cavity.

When the Coil Sheath is Damaged

1. Loosen the Clamping Screw of the Handle by turning it counterclockwise until it stops.
2. Push the Ratchet Stopper of the Handle to release it.
3. Turn the Rotatable Bar towards you to detach the Handle.
4. Perform open surgery or other possible treatment.

Chapter 5 Reprocessing

WARNING

The instrument was not sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions in this Chapter.
Do not use an instrument that has not been cleaned and sterilized. This poses an infection control risk or cause tissue irritation.

5.1 General Policy

- The medical literature reports incidents of patient cross contamination resulting from improper cleaning or sterilization. It is strongly recommended that reprocessing personnel have a thorough understanding of and follow all national and local hospital guidelines and policies.
  A specific individual or individuals in the endoscopy unit should be responsible for reprocessing endoscopic equipment. It is highly desirable that a trained backup be available should the primary reprocessing individual(s) be absent.
- All individuals responsible for reprocessing should thoroughly understand:
  - your institution’s reprocessing procedures
  - occupational health and safety regulations
  - national and local hospital guidelines and policies

- the instructions in this manual
- the mechanical aspects of endoscopic equipment
- pertinent germicide labeling

Olympus Endo-Therapy Accessories are compatible with 2.0 – 3.2% glutaraldehyde solution. However, routine biological monitoring is not feasible with glutaraldehyde and, therefore, it should not be used to sterilize reusable medical devices that are compatible with other methods of sterilization that can be biologically monitored, such as steam sterilization.

WARNING

- Failure to properly clean and sterilize the instrument after each examination can compromise patient safety. During use, the instrument normally comes in contact with intact mucous membranes. To minimize the risk of transmitting diseases from one patient to another, after each examination the instrument must undergo thorough manual cleaning followed by sterilization.
- If the instrument is not cleaned meticulously, effective sterilization cannot be obtained. Clean the instrument thoroughly before sterilization to remove microorganisms or organic material which can limit the effectiveness of the sterilization process.

- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and infectious material. During cleaning and sterilization, always wear appropriate personal protective equipment, such as eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Always remove contaminated protective clothing before leaving the reprocessing area.
- The reprocessing procedures described in this manual should be completed the same day the instrument has been used. If reprocessing is delayed, residual organic debris will solidify and it may be difficult to effectively reprocess the instrument.
- With the cleaning and sterilization methods stated in this instruction manual, prions, which are considered to be the pathogenic substance of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated. When using this instrument on a patient with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use this product for such patient only and/or immediately dispose of this product after use in an appropriate manner. For methods to handle CJD, please follow the respective guidelines in your country.

- This instrument is not durable, or does not have sufficient durability against the respective methods stated in the guidelines of each country for destroying or inactivating prions. For information on the durability against each method, please contact Olympus. If cleaning and sterilization methods not stated in this instruction manual are performed, Olympus cannot guarantee the effectiveness, safety and durability of this instrument. Make sure to confirm that there is no abnormality before use, and use under responsibility of a physician. Do not use if any abnormality is found.

5.2 Required Reprocessing Equipment

Wear the personal protective equipment as specified in the Table on page 38.

1. Prepare the following equipment. The required amount of detergent solution, lubricant and other equipment depends on the number of instruments to be reprocessed.
2. Fill an immersion basin with detergent solution and fill a second immersion basin with lubricant at the temperatures and concentrations recommended by the manufacturers. Also fill the ultrasonic cleaner with a detergent solution appropriate for ultrasonic cleaning.

Equipment Needed for Reprocessing

To perform proper reprocessing, the equipment in the following Table is required. For details on preparation and directions for use of the following equipment, refer to the respective instruction manuals or contact the equipment manufacturer.

Contact Olympus for the names of specific brands of detergent solutions and lubricants.

Equipment Needed

Protective Equipment	Appropriate personal protective equipment may include: Eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves.
Immersion Basin for Detergent Solution	Use a basin with a depth and diameter large enough to allow complete immersion of the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cm.
Detergent Solution for Immersion	Use a neutral pH, low-foaming, medical-grade detergent solution.
Ultrasonic Cleaner	Use a medical grade ultrasonic cleaner with a frequency range of 38 – 47 kHz, and with a depth and a diameter large enough to allow complete immersion of the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cm. Compatible ultrasonic cleaners include OLYMPUS ULTRASONIC CLEANER KS-2.
Detergent Solution for Ultrasonic Cleaning	Use a neutral pH, low-foaming, medical-grade detergent solution with no abrasive.

Immersion Basin for Lubricant	Use a basin with a depth and diameter large enough to allow complete immersion of the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cm.
Lubricant	Use a medical-grade water soluble or low-viscosity emulsion type lubricant.
Lint-free Cloths	
Packages for Steam Sterilization	Use packages compatible with steam sterilization (autoclaving). The packages should be large enough to accommodate the instrument when the Insertion Portion is coiled with a diameter of not less than 15 cm.
Sealing Device for Packages	Sealing the packages may require a device such as a heat sealer. Prepare an appropriate sealing device according to the packages to be used.
Autoclave	Use an autoclave that will operate at the conditions specified in Section 5.5, “Sterilization”.

5.3 Cleaning

WARNING

When cleaning, avoid exposure to the reprocessing chemicals. They may pose an infection control risk or cause skin irritation.

CAUTION

- Due to this instrument’s construction, the Ratchet Stopper of the Handle has a sharp tip. To avoid injury, be very careful when handling this instrument.
- When reprocessing, do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.

Immersion

WARNING

Immerse the instrument in detergent solution immediately after use. If the instrument is not cleaned immediately, it may be difficult to effectively reprocess, and this could result in reduced performance.

1. Immerse the entire instrument in the detergent solution for the time specified in manufacturer's instructions. If no time is specified, immerse for between 5 minutes and 3 hours.
2. Remove the instrument from the detergent solution.

Ultrasonic Cleaning

1. Immerse the entire instrument in detergent solution.
2. Clean ultrasonically for 30 minutes. For details on operation of the ultrasonic cleaner, refer to the instruction manual of the ultrasonic cleaner.
3. Remove the instrument from the detergent solution.

Rinsing

CAUTION

- After ultrasonic cleaning, rinse the instrument thoroughly to remove residual detergent. Residual detergent solution could cause tissue irritation in the next patient.
- Do not forcefully squeeze, wipe or scrub the instrument. This could cause damage to the instrument or result in reduced performance.

1. Rinse the instrument under clean running tap water.
2. Confirm that no debris is left on the surfaces of the instrument.
3. Wipe the exterior of the instrument with a clean, dry lint-free cloth.

5.4 Lubrication

WARNING

When lubricating, avoid exposure to the lubricant. It may pose an infection control risk or cause skin irritation.

CAUTION

- Do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.
- Due to this instrument's construction, the Ratchet Stopper of the Handle has a sharp tip. To avoid injury, be very careful when handling this instrument.

1. Immerse the entire instrument in the lubricant for 2 – 3 seconds.
2. Remove the instrument from the lubricant.
3. Turn the Rotatable Bar of the Handle two or three times.
4. Wipe the exterior of the instrument with a clean, dry lint-free cloth and allow the instrument to air dry.

5.5 Sterilization

Sealing the Package

CAUTION

Do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.

1. Before sterilization, the instrument must be thoroughly cleaned and dried. Residual moisture inhibits sterilization.
2. Coil the Insertion Portion and place the Coil Sheath in the package.
3. Place the Handle in a separate package.
4. Seal the packages. For details on sealing, refer to the instruction manual of the package and the sealing device.

Steam Sterilization (Autoclaving)

WARNING

- Use biological indicators as recommended by your hospital's policy and follow the manufacturer's instructions, all national and local hospital guidelines and policies.
- Always leave space between the packages in the autoclave. If the packages are placed too close together, effective sterilization will not be possible.
- Allow the packages to dry within the autoclave using the autoclave's drying cycle (if applicable) or by opening the door of the autoclave and allowing the packages to air dry. Handling a wet package can compromise its sterility.

- The results of sterilization depend on various factors such as how the sterilized instrument was packed or the positioning, method of placing and loading of the instrument in the sterilization device. Please verify the sterilization effects by using biological or chemical indicators. Also follow the guidelines for sterilization issued by medical administrative authorities, public organizations or the infection management sections at each medical facility, as well as the instruction manual of the sterilization device.

1. Place the sealed package containing the instrument in the autoclave and sterilize in accordance with the conditions listed below. For details on operation of the autoclave, refer to the instruction manual for the autoclave or other manufacturer instructions.
2. After steam sterilization, let the instrument gradually cool down to room temperature. Sudden changes in temperature may damage the instrument.

NOTE

Autoclavable products have a green reference label. Products that do not have green reference labels are not autoclavable.

	Temperature	Exposure Time
Prevacuum	132 – 134°C (270 – 274°F)	5 minutes

Table 5.1 Recommended Steam Sterilization (Autoclaving) Conditions

Chapter 6 Storage

WARNING

- Do not store the instrument in a sterile package that is damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised and pose an infection control risk or cause tissue irritation.
- Do not store the sterile packages containing the instrument in place where they will be damaged, wet or improperly sealed. Otherwise, the sterility of the instrument may be compromised and pose an infection control risk or cause tissue irritation.

CAUTION

Do not coil the Insertion Portion with a diameter of less than 15 cm. This could damage the Insertion Portion.

6.1 Inspection Before Storage

Prior to storage, inspect the sterile packages as follows:

Confirm that the sterile packages containing the instrument are free from tears, inadequate sealing or water damage. If tears, inadequate sealing or water damage is detected, repackage and sterilize again as described in Section 5.5, “Sterilization”.

6.2 Storage

Store the instrument in sterile packages at room temperature in a clean and dry environment. Do not store them in direct sunlight. Ensure that the packaged instrument is not crushed by surrounding objects during storage. Follow any additional storage instructions provided by the manufacturer of the sterile package.

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